

REMARKS

Attached hereto is a marked-up version of the changes made to the specification by the above amendment. The attached page is captioned **“Version with markings to show changes made.”**

The amendment to claim 1 merely clarifies the use of the term “photosensitizer” and does not alter the scope of the claim. The amendment also introduces language from page 9, lines 19-22, which describes a feature of the methods of the invention. The language does not alter the scope of the claims but rather recites a feature already present in the claim as originally presented. The amendment is also made for reasons relating to business considerations and commercial applications rather than issues of patentability. No new matter has been added and entry of the amendment is respectfully requested.

Objection to claim 1

Claim 1 has been objected to for an asserted informality in the use of “PS” as an abbreviation for the term “photosensitizer” as indicated by the use of “(PS)” after the first use of “photosensitizer”. No basis for why this usage, which occurs in similar fashion in numerous other claims found in issued patents, is considered “informal”.

While Applicants believe that the use of the abbreviation introduces no ambiguity or concern in the claim as filed, claim 1 has been amended to use the full term “photosensitizer” without the benefit of the abbreviation. Reconsideration and withdrawal of this objection is respectfully requested.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 1-6 and 9-10 are rejected under 35 U.S.C. § 112, first paragraph as allegedly enabled by the specification for only the photosensitizers recited on specific portions of the application. Applicants have carefully reviewed the statement of this rejection as well as the standards for objective enablement and respectfully traverse as follows.

As an initial matter, Applicants would like to point out that MPEP 2164.04 sets forth the standard of *In re Marzocchi* (169 USPQ 367 (CCPA 1971)) that claims must be taken as being enabled unless there is reason to doubt the objective truth of the statements of an application in support of enablement. Applicants respectfully submit that no adequate reasons have been provided.

Instead, the statements closest to bases to doubt the objective truth in the ability to use photosensitizers in the instant methods are the assertions that different porphyrin derivatives “may be expected to yield a different result” and that different photosensitizer compounds “may be reasonably expected to yield a different result in restenosis or intimal hyperplasia.” These statements are followed by the assertion that this indicates “unpredictability” which would result in the need for undue experimentation to practice the invention as claimed.

Applicants point out, however, that despite the differences between different porphyrin derivatives and photosensitizer compounds, there is a common feature that has apparently been overlooked but makes all of them reasonable for the practice of the invention as claimed. This feature is the simple requirement that they be photosensitizers (or, stated differently, be capable of photoactivation). This is a requirement for the claims as presented, and would lead a skilled artisan to expect that any porphyrin derivative or other photosensitizer, as long as it possesses

photosensitizing activity, would be suitable for the practice of the invention. The statement of the rejection apparently overlooks this critical point.

Additionally, the assertion of “unpredictability” leading to undue experimentation does not appear to be adequately supported. While it is possibly “unpredictable” as to whether a particular new photosensitizer will function in the claimed methods (in the sense of something that is not known with absolute certainty), this does not necessarily lead to the requirement for undue experimentation. As disclosed in the specification and known in the art, the use of a photosensitizer requires its administration at a certain dosage followed by irradiation of a certain wavelength and power to activate it. Thus the actual amount of experimentation to determine the conditions for the use of any photosensitizer only requires routine (or repetitive) practice of a limited number of parameters rather than any experimentation and design for *de novo* discovery. Such repetitive experimentation is completely within the limits permitted by the standards for objective enablement.

Lastly, and to the extent that the rejection may be based upon a view that some inoperative embodiments may exist, Applicants respectfully point out that the presence of inoperative embodiments within a claim is permitted under established standards for enablement.

In light of the above, Applicants respectfully submit that the rejection as presented is misplaced and may be properly withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

Claim 8 is rejected under 35 U.S.C. § 112, second paragraph as allegedly containing the impermissible use of trademarks. Applicants have carefully reviewed the statement of this rejection as well as the standards for objective enablement and respectfully traverse as follows.

Simply put, the terms BPD-MA and A-EA6 are not trademarks. They are simply designations used to identify specific benzoporphyrin derivatives as known in the art. Accordingly, and because the actual structures of the compounds are described on pages 37, line 3 to page 40, line 2, the use of the terms raise no issue under 35 U.S.C. § 112, second paragraph and the rejection may be properly withdrawn.

Rejection under 35 U.S.C. § 103(a)

Claims 1-10 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Vincent et al. and Adili et al. Applicants have carefully reviewed the statement of this rejection as well as the contents of the cited reference and traverse as follows.

As an initial matter, Applicants note that the instant rejection is based upon combining a reference (Vincent et al.) that teaches the use of photosensitizers *without the use of photoactivation* and a second reference (Adili et al.) that teaches the use of photosensitizers *with photoactivation*. It thus appears that the combination requires that an essential element of Vincent et al. (the absence of photoactivation) be ignored. This would seem to destroy the teachings of Vincent et al. It also seems that Vincent et al. relates to a non-analogous area concerning photosensitizers that is wholly separate from the instant claims which require the use of photoactivation.

Nevertheless, and in full response to the instant rejection, claim 1 has been amended to recite that the method is conducted without the depletion of all endothelial and smooth muscle cells. To the contrary, Adili et al. teach that their conditions result in an “acellular media even 21 days after PDT” (see page 272, last sentence of first full paragraph).

Thus Adili et al. do not teach conditions that result in the methods of the amended claims. Moreover, and as noted above, Vincent et al. is directed to an area non-analogous to the instant invention.

Applicants thus respectfully submit that the references, alone or in combination, do not teach or suggest the invention as claimed, and this rejection may be properly withdrawn.

CONCLUSION

In light of the above amendments and remarks, Applicants believe that the claims are now in condition for allowance and urge passage of the application to issue. The Examiner is invited to contact Applicants' agent at the number listed below if it would be helpful in any way to resolve any remaining issues.

In the event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 273012012200. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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Kindly amend the claims as follows:

1. (amended) A method to prevent, treat, inhibit, or reduce restenosis or intimal hyperplasia in adjunct with angioplasty in a human subject, which method comprises
 locally administering an effective amount of one or more photosensitizer (~~PS~~) to a blood vessel site that has undergone angioplasty, and
 irradiating said site with radiation containing one or more wavelength(s) absorbed by said one or more ~~PS~~ photosensitizer for a time and at an intensity to prevent, treat, inhibit, or reduce restenosis or intimal hyperplasia at said site without depleting all endothelial and smooth muscle cells,
 wherein the concentration of said one or more ~~PS~~ photosensitizer, the intensity of the radiation, and the total energy provided are adjusted to provide said site with low dose photodynamic therapy.